

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 18, “Centralized Prescription Filling and Processing,” Iowa Administrative Code.

These proposed amendments were approved at the November 1, 2017, regular meeting of the Board of Pharmacy.

Pursuant to Iowa Code section 17A.7(2), the Board has completed an overall review of this chapter of administrative rules. The proposed amendments clarify records requirements and update language to be consistent with other Board rules. The proposed amendments would remove the implication that central fill pharmacies can only enter into agreements with pharmacies that are in good standing. The proposed amendments also remove redundancies in rules that exist in other applicable chapters of Board rules.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 19, 2018. Such written materials may be sent to Terry Witkowski, Executive Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by email at terry.witkowski@iowa.gov.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

After analysis and review of this rule making, no impact on jobs is anticipated.

These amendments are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.13, and 155A.28.

The following amendments are proposed.

ITEM 1. Amend rule 657—18.3(155A) as follows:

657—18.3(155A) General requirements.

18.3(1) Essential qualifications. An originating pharmacy may outsource prescription drug filling to a central fill pharmacy or prescription drug order processing to a central processing pharmacy provided the pharmacies:

a. Have the same owner or have entered into a written contract or agreement, which is available for inspection and copying by the board or its authorized agent, that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and

b. No change.

18.3(2) No change.

18.3(3) Originating pharmacy responsibility. Except as specifically provided by this subrule, the originating pharmacy shall be responsible for all dispensing functions as the term “dispense” is defined in rule 657—18.2(155A). An originating pharmacy contracting only for centralized filling shall retain responsibility for all processing functions, and an originating pharmacy contracting only for centralized processing shall retain responsibility for all filling functions.

a. No change.

b. A central fill or a central processing pharmacy that shares a common central processing unit with the originating pharmacy may perform prospective drug use review (DUR) pursuant to rule 657—8.21(155A). Only a pharmacist shall perform the DUR; ~~the~~ and such review shall not be

delegated to a pharmacy technician, registered nurse, or other pharmacy support person. The pharmacist performing the DUR shall document in the shared patient record all concerns, recommendations, observations, and comments resulting from that review. The pharmacist at the originating pharmacy shall utilize the DUR notes in counseling the patient pursuant to rule 657—6.14(155A).

18.3(4) Central fill label requirements. The label affixed to the prescription container filled by a central fill pharmacy on behalf of an originating pharmacy shall include the following:

a. to h. No change.

i. The initials or other unique identification of the pharmacist in the originating pharmacy who performed drug use review and transmitted the prescription drug order to the central fill pharmacy.

ITEM 2. Amend subrule 18.5(2) as follows:

18.5(2) Exception. The provisions of this rule do not apply to a patient in a facility, such as a hospital or long-term care facility, where Iowa law requires that drugs be administered to the patient by a health care professional.

ITEM 3. Amend rule 657—18.10(155A) as follows:

657—18.10(155A) Policy and procedures.

~~**18.10(1) Manual maintained.**~~ Pursuant to rule 657—8.3(155A), a policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or an its authorized agent of the board.

~~**18.10(2) Manual contents.**~~ The manual shall:

~~a. 1.~~ Outline the responsibilities of each of the pharmacies;

~~b. 2.~~ Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or centralized processing; and

~~c. —Include evidence that all licenses and registrations have been verified to be current and in good standing, identifying the individual verifying license and registration status and the method used to verify status; and~~

~~d. 3.~~ Include, but not necessarily be limited to, policies and procedures for:

(1) • Protecting the confidentiality and integrity of patient information;

(2) • Protecting each patient's freedom of choice of pharmacy services;

(3) • Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or centralized processing function; and

(4) —Complying with federal and state laws, rules, and regulations;

(5) • Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(6) —Reviewing, at least annually, the written policies and procedures and documenting that review.

ITEM 4. Amend rule 657—18.15(155A) as follows:

657—18.15(155A) Records. Central fill or central processing pharmacies shall maintain appropriate records that identify, by prescription drug order, the ~~name and~~ initials or unique identification code of each pharmacist or pharmacy technician who performs a centralized filling or centralized processing function for a prescription drug order. Originating pharmacies shall maintain appropriate records that identify, by prescription drug order, the ~~name and~~ initials or unique identification code of the pharmacist who performed drug use review and the pharmacist who transmitted the prescription drug order to the central fill or central processing pharmacy. These records may be maintained separately by each pharmacy or in a common electronic file as long as the data processing system is capable of producing a printout that lists the functions performed by each pharmacy and pharmacist or technician and identifies the pharmacist or technician who performed each function.